

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant :	Thomas S. Wilson et al	Docket No. :	IL-11176
Serial No. :	10/801,355	Art Unit :	3731
Filed :	03/15/2004	Examiner :	Kathleen C. Sonnett
For :	SHAPE MEMORY POLYMER FOAMS FOR ENDOVASCULAR THERAPIES		

Honorable Commissioner for Patents  
Alexandria, VA 22313-1450

Attention: Board of Patent Appeals and Interferences

Dear Sir:

APPELLANTS' BRIEF (37 C.F.R. § 1.192)

(Replacement Brief Responsive to Non-Compliant Notice Mailed 03/06/2008)

This brief is submitted in support of Appellants' notice of appeal from the Final Rejection, filed October 17, 2007 finally rejecting claims 1-56 of the subject application.

Appellants' notice of appeal was filed January 3, 2008.

One copy of the brief is being transmitted per 37 C.F.R. § 41.37.

This is a Replacement Appeal Brief responsive to the Notification of Non-Compliant Appeal Brief Mailed 03/06/2008.

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### **I. REAL PARTY IN INTEREST**

The real party in interest is:

Lawrence Livermore National Security, LLC and the United States of America as represented by the United States Department of Energy (DOE) by virtue of an assignment by the inventor as duly recorded in the Assignment Branch of the U.S. Patent and Trademark Office.

### **II. RELATED APPEALS AND INTERFERENCES**

There are no related appeals or interferences.

### **III. STATUS OF CLAIMS**

The application as originally filed contained claims 1-56.

The claims on appeal are claims 1-56.

The status of all the claims in the proceeding (*e.g.*, rejected, allowed or confirmed, withdrawn, objected to, canceled) is:

Claims 1-56 are rejected.

Claims 1-56 on appeal are reproduced in the Appendix.

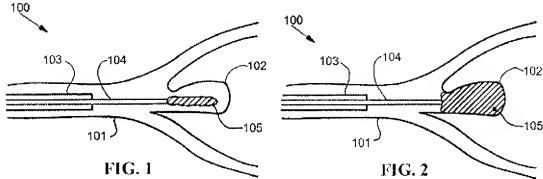
### **IV. STATUS OF AMENDMENTS**

There have been no amendments filed subsequent to the Final Rejection mailed October 17, 2007.

## V. SUMMARY OF CLAIMED SUBJECT MATTER

Appellants' invention is summarized in paragraph [0007] on page 4, lines 1-2 of Appellants' original specification as follows: "The present invention provides a system for occluding a physical anolmaly." The Merriam-Webster OnLine dictionary defines "occluding" as: "to close up or block off." Appellants' invention is therefore for "occluding (to close up or block off) a physical anolmaly." The primary Maitland et al reference used in the Final Rejection against Appellants' claims is not for occluding, i.e., to close up or block off, a physical anolmaly. Instead the prior art Maitland et al reference cited in the Final Rejection is for removing a clot in a vein or in an artery.

Appellants' invention is illustrated in FIGS. 1 and 2 and described in paragraphs [0021], [0022], [0023], [0025], and [0026] of Appellants' original specification reproduced below.



[0021] Referring now to FIGS. 1 and 2, two figures will be used to describe an embodiment of the present invention that provides a system for occluding a physical anolmaly. The embodiment is designated generally by the reference numeral 100. FIGS. 1 and 2 are schematic illustrations of the working end of a system 100 for treating an arteriovenous malformation or aneurysm 102. (Page 9, lines 10-14 of Appellants' original specification)

[0022] As shown in FIG. 1, a collapsed SMP foam device 105 is connected at the end of a guide wire 104. The SMP foam device 105 is placed inside the aneurysm 102. This is accomplished by delivering the SMP foam device 105 through a catheter 103 using the guide wire 104. The catheter 103 is inserted

through the artery 101 to position the SMP foam device 105 in the aneurysm 102. (Page 9, lines 20-26 and page 10, lines 1-2 of Appellants' original specification)

[0023] Referring now to FIG. 2 the SMP foam device 105 is shown actuated, thereby expanding it inside the aneurysm 102 and occluding the aneurysm 102. The SMP foam device 105 is expandable from 100% to 10000% in volume. The SMP foam device 105 is actuated by one of several means including electromagnetic energy delivered optically. The SMP foam device 105 is used to occlude part or all of a lumen, aneurysm, or arteriovascular malformation. The expanded SMP foam device 105 is releasing from the end of the guide wire 104. The guide wire 104 is then retracted through the catheter 103. The catheter 103 is then retracted from the artery 101. (Page 10, lines 3-8 of Appellants' original specification)

[0025] The present invention has uses wherever it is desirable to occlude a physical anomaly. For example, the present invention has use for the closure of an aneurysm for the prevention and/or treatment of a stroke. (Page 10, lines 24-26 of Appellants' original specification)

[0026] Stroke is a major cause of mortality and the primary cause of long-term disability in the United States. Each year there are an estimated 700,000 occurrences of stroke, from which 150,000 people die and 400,000 are left with a significant deficit. The costs of caring for victims of stroke in the acute phase, for chronic care, and lost productivity amount to an estimated \$40 billion per year. Approximately 20% of strokes are hemorrhagic and result from the rupture of either arteriovenous malformations (AVMs) or aneurysms. For aneurysm/AVM rupture, the incidence of death is about 29%, and an additional 20 to 30% of patients suffer neurologic deficits. Since an estimated 4% of aneurysm/AVMs rupture each year, a significant number of people (up to 3.5 million) have aneurysm/AVMs for years prior to stroke occurrence, indicating significant benefit from early preventative treatment. (Page 11, lines 1-12 of Appellants' original specification)

There are three (3) independent claims on appeal. Appellants' independent claims on appeal are claims 1, 23, and 45. Appellants' independent claims 1, 23, and 45 on appeal are "read on" Appellants' original specification below. Portions of Appellants' specification are quoted and the paragraph containing the quote is identified by the page and line numbers.

### Claim 1

An apparatus for endovascular therapy by occluding a physical anomaly, said anomaly having an interior, comprising:

a shape memory material body for positioning in the interior of the physical anomaly, wherein said shape memory material body comprises a shape memory polymer foam;

a delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly; and

a system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape for occluding the physical anomaly and a secondary shape for being delivered into the interior of the physical anomaly.

### Specification & Drawings

The present invention provides a system for occluding a physical anomaly. (Page 4, lines 1-2)

One embodiment of the present invention comprises a shape memory material body wherein the shape memory material body fits within the physical anomaly occluding the physical anomaly. ... In another embodiment, the shape memory material body comprises a shape memory polymer foam. (Page 4, lines 1-9)

The SMP foam device 105 is placed inside the aneurysm 102. This is accomplished by delivering the SMP foam device 105 through a catheter 103 using the guide wire 104. (Page 9, lines 16-18)

The SMP foam device 105 is placed inside the aneurysm 102. ... Referring now to FIG. 2 the SMP foam device 105 is shown actuated, thereby expanding it inside the aneurysm 102 and occluding the aneurysm 102. ... The SMP foam device 105 is made out of "shape memory polymer" (SMP). The SMP is a material which can be formed into a specific "primary" shape, reformed into a "secondary" stable shape, then controllably actuated so that it recovers its primary shape. (Page 9, lines 16-18)

### Claim 23

An apparatus for endovascular therapy by occluding an aneurism having an interior, comprising:

shape memory polymer material body for being positioned in the interior of the aneurism, wherein said shape memory polymer material body comprises a shape memory polymer foam;

a delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism; and

an activation system for providing said shape memory polymer material body with a primary shape for occluding the aneurism and a secondary shape for being positioned in the interior of the aneurism.

### Specification & Drawings

The general concept behind the SMP foam device for aneurism therapy will be summarized with reference to FIGS. 1 and 2. (Page 10, lines 9-10) The present invention has uses wherever it is desirable to occlude a physical anomaly. (Page 4, lines 24-25)

a shape memory material body wherein the shape memory material body fits within the physical anomaly occluding the physical anomaly. ... In another embodiment, the shape memory material body comprises a shape memory polymer foam. (Page 4, lines 1-9)

The SMP foam device 105 is placed inside the aneurysm 102. This is accomplished by delivering the SMP foam device 105 through a catheter 103 using the guide wire 104. (Page 9, lines 16-18)

The SMP foam device 105 is placed inside the aneurysm 102. ... Referring now to FIG. 2 the SMP foam device 105 is shown actuated, thereby expanding it inside the aneurysm 102 and occluding the aneurysm 102. ... The SMP foam device 105 is made out of "shape memory polymer" (SMP). The SMP is a material which can be formed into a specific "primary" shape, reformed into a "secondary" stable shape, then controllably actuated so that it recovers its primary shape. (Page 9, lines 16-18)

#### Claim 45

An endovascular therapy method for occluding a physical anomaly, the physical anomaly having an interior, comprising the steps of:

providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly,

positioning said shape memory polymer material body comprising a shape memory polymer foam in the interior of the physical anomaly when said shape memory polymer material body is in said secondary shape, and

causing said shape memory polymer material body comprising a shape memory polymer foam to change to said larger primary shape for occluding the anomaly.

#### Specification & Drawings

The general concept behind the SMP foam device for aneurysm therapy will be summarized with reference to FIGS. 1 and 2. (Page 10, lines 9-10)  
The present invention has uses wherever it is desirable to occlude a physical anomaly. (Page 4, lines 24-25)

a shape memory material body wherein the shape memory material body fits within the physical anomaly occluding the physical anomaly. ... In another embodiment, the shape memory material body comprises a shape memory polymer foam. (Page 4, lines 1-9)

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## **VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

The Final Rejection mailed October 17, 2007 states nine (9) grounds of rejection. The nine grounds of rejection are summarized as follows:

**Grounds of Rejection #1** - Claims 1, 3, 4, 6-15, 21-23, 25-37, 43, and 44 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Maitland et al. (200210095169) in view of Bleys et al. (US 6,034,149). The rejection is stated in numbered paragraphs 7-17 of the Final Rejection mailed October 17, 2007.

**Grounds of Rejection #2** - Claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47, and 49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamiya et al. (U.S. 5,192,301) in view of Bleys et al. (US 6,034,149). The rejection is stated in numbered paragraphs 18-23 of the Final Rejection mailed October 17, 2007.

**Grounds of Rejection #3** - Claims 2 and 24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Maitland et al. (200210095169) in view of Bleys et al. (US 6,034,149) and further in view of Picha (US 5,207,709). The rejection is stated in numbered paragraphs 24-25 of the Final Rejection mailed October 17, 2007.

**Grounds of Rejection #4** - Claims 2, 24, and 46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamiya et al. (U.S. 5,192,301) in view of Bleys et al. (US 6,034,149) and further in view of Picha (US 5,207,709). The rejection is stated in numbered paragraphs 26-27 of the Final Rejection mailed October 17, 2007.

**Grounds of Rejection #5** - Claims 5 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamiya et al. (U.S. 5,192,301) in view of Bleys et al. (US

6,034,149) and further in view of Linden et al. (US 5,634,936). The rejection is stated in numbered paragraphs 28-29 of the Final Rejection mailed October 17, 2007.

**Grounds of Rejection #6** - Claims 17-20 and 39-42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamiya et al. (U.S. 5,192,301) or Maitland et al. (200210095169) in view of Bleys et al. (US 6,034,149) and further in view of Porter (US 2002/0165582). The rejection is stated in numbered paragraphs 30-32 of the Final Rejection mailed October 17, 2007.

**Grounds of Rejection #7** - Claims 48 and 50-52 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamiya et al. (U.S. 5,192,301) in view of Bleys et al. (US 6,034,149) and further in view of Maitland et al. (200210095169). The rejection is stated in numbered paragraphs 33-34 of the Final Rejection mailed October 17, 2007.

**Grounds of Rejection #8** - Claims 53-56 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamiya et al. (U.S. 5,192,301) in view of Bleys et al. (US 6,034,149) and further in view of Porter (US 2002/0165582). The rejection is stated in numbered paragraphs 35-37 of the Final Rejection mailed October 17, 2007.

**Grounds of Rejection #9** - Claims 53-56 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Maitland et al. (200210095169). The rejection is stated in numbered paragraphs 38-39 of the Final Rejection mailed October 17, 2007.

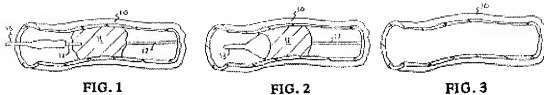
## VII. ARGUMENT

### Argument Relating to the Grounds of Rejection #1

Claims 1, 3, 4, 6-15, 21-23, 25-37, 43, and 44 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Maitland et al. (hereinafter Maitland) in view of Bleys et al. (hereinafter Bleys) in Grounds of Rejection #1.

### The Maitland Reference

The Maitland reference is a system for removing a clot in a vein or in an artery. Note in particular that the Maitland reference is not a system for occluding, closing up or blocking off, a physical anomaly as claimed in Appellants' claims on appeal. The Maitland reference is illustrated in FIGS. 1, 2, and 3 and described in the Maitland specification reproduced below.



[0056] FIG. 1 shows a vessel 10 with a blockage 11. The blockage could be a blood clot, plaque, other emboli, or other blockage. A support structure 12 with a shape memory material actuator 13 on its distal end is inserted through or around the blockage 11. The shape memory material actuator 13 is used to remove the blockage 11 from the vascular system.

[0057] FIG. 2 shows the expanded shape memory material actuator 13. Actuation is achieved by heating the shape memory material.

[0058] FIG. 3 shows that, when the shape memory material actuator is drawn backward it results in the removal of the blockage from the vessel 10. The catheter with the shape memory material 13 was transported to the site of the matter 11 to be removed. The shape memory material 13 was passed through or around the matter 11. Heat was utilized to activate the shape memory material 13 and expand the shape memory material 13. By withdrawing the support structure 12 and the shape memory material 13 through the vessel 10 the matter 11 was carried from the vessel 10.

### Appellants Disagree with Examiners' Findings of Fact

Appellants disagree with the Examiner's Findings of Fact in the Final Rejection regarding the Maitland reference. The Final Rejection in numbered paragraph 7 states, "Maitland et al. discloses an apparatus for occluding a physical anomaly comprising a shape memory polymer for positioning in the interior of the physical anomaly and a system for providing the shape memory polymer with a primary shape for occluding the physical anomaly and a secondary shape for being positioned in interior of the physical anomaly (see abstract)."

The Maitland reference does not disclose an apparatus for (1) occluding a physical anomaly, or (2) for positioning in the interior of the physical anomaly, or (3) providing the shape memory polymer with a primary shape for occluding the physical anomaly and a secondary shape for being positioned in interior of the physical anomaly.

The Maitland reference completely fails to disclose an apparatus for closing up or blocking off a physical anomaly such as an aneurism as claimed in Appellants' claims on appeal. Instead of occluding a physical anomaly (closing up or blocking off) by positioning a shape memory material body in the interior of the physical anomaly; the Maitland reference removes a clot in a vein or in an artery.

The Maitland reference is basically the opposite of Appellants' claimed invention in that the Maitland reference removes a clot whereas Appellants' claimed invention inserts a shape memory material body in an aneurism.

### The Bleys Reference

The Bleys reference "is concerned with hydrophilic flexible polyurethane foams" (Col. 1, lines 2-3 of the Bleys reference). In the Bleys reference, "The foams as described above then are compressed, preferably after they have been

dried. The degree of compression depends on the thickness reduction desired. Preferably the thickness reduction is such that the thickness of the compressed foam in the absence of a force suitable to create the compressed state is at most 90%, more preferably at most 70% and most preferably at most 60% of the thickness of the foam before it was compressed. Since the foam might recover slightly after the force, applied to create the compressed state, has been removed the compression is conducted in such a way that the thickness of the foam when the compression is applied is 0-50 and preferably 0-30% lower than the above figures for the thickness of the foam after the force suitable for creating the compressed state has been removed. The compression may be conducted in one or more of the dimensional directions of the foam. Although in general not necessary, the compression may be repeated after decompression. The compression may be conducted by applying any force suitable like compression of the foam between two or more flat plates, two or more rollers or two conveyor belts." (Col. 6, lines 57-67 and Col. 7, lines 1-10 of the Bleys reference)

*Prima Facie Case of Obviousness Has Not Been Established*

The rejection of claims 1, 3, 4, 6-15, 21-23, 25-37, 43, and 44 as being obvious over Maitland in view of Bleys in Grounds of Rejection #1 does not establish a *Prima Facie* case of obviousness. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) include, "Ascertaining the differences between the prior art and the claims at issue." The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). Three basic criteria must be met in order for the Examiner to establish a *prima facie* case of obviousness. The prior art reference (or reference when combined) must teach or suggest all the claim limitations. There must be a reasonable expectation of success with the

proposed combination. The Examiner must follow the “Examination Guidelines for Determining Obviousness in Light of the Supreme Court’s KSR v. Teleflex Decision” published October 10, 2007. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

The Maitland and Bleys References Do Not Teach All Claim Limitations

The criteria that prior art reference, or references when combined, must teach or suggest all the claim limitations has not been met. The Maitland and Bleys references fail to teach most of Applicants’ claim limitations. The Maitland and Bleys references do not teach the limitations of Applicants’ claims 1, 3, 4, 6-15, 21-23, 25-37, 43, and 44 identified below.

Claim 1 – “An apparatus for endovascular therapy by occluding a physical anomaly, said anomaly having an interior,” or

Claim 1 – “a shape memory material body for positioning in the interior of the physical anomaly, wherein said shape memory material body comprises a shape memory polymer foam,” or

Claim 1 – “a delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly,” or

Claim 1 – “a system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape for occluding the physical anomaly and a secondary shape for being delivered into the interior of the physical anomaly,” or

Claim 6 – “The apparatus of claim 1 wherein said shape memory polymer foam is a shape memory polymer foam with an open cell foam structure including a light absorbing dye,” or

Claim 7 – “The apparatus of claim 1 wherein said delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly includes a delivery catheter, a guide wire having an end, and wherein said shape

memory material body that comprises a shape memory polymer foam is at said end of said guide wire," or

Claim 9 – "The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises radiology," or

Claim 9 – "The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises electromagnetic energy," or

Claim 10 – "The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises electromagnetic energy delivered optically," or

Claim 11 – "The apparatus of claim 1 wherein said shape memory material body that comprises a shape memory polymer foam is a collapsed shape memory polymer foam device connected at the end of a guide wire," or

Claim 12 – "The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a system for optical heating using optic fibers to transport light energy to said shape memory material body that comprises a shape memory polymer foam," or

Claim 13 – "The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a laser and an optical fiber wherein said laser transmits laser light through said optical fiber," or

Claim 14 – "The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a laser and an optical fiber wherein said laser transmits laser light through a multimode optical fiber," or

Claim 15 – "The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a light absorbing material," or

Claim 21 – “The apparatus of claim 1 wherein said shape memory material body that comprises a shape memory polymer foam comprises a shape memory polymer body that comprises a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly,” or

Claim 22 – “The apparatus of claim 1 wherein said shape memory material body that comprises a shape memory polymer foam comprises a shape memory polymer foam body having a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly,” or

Claim 23 – “An apparatus for endovascular therapy by occluding an aneurism having an interior,” or

Claim 23 – “shape memory polymer material body for being positioned in the interior of the aneurism, wherein said shape memory polymer material body comprises a shape memory polymer foam,” or

Claim 23 – “a delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism,” or

Claim 23 – “an activation system for providing said shape memory polymer material body with a primary shape for occluding the aneurism and a secondary shape for being positioned in the interior of the aneurism,” or

Claim 26 – “The apparatus of claim 23 wherein said shape memory polymer material body that comprises a shape memory polymer foam is a shape memory polymer foam with an open cell foam structure including a light absorbing dye,” or

Claim 27 – “The apparatus of claim 23 wherein said delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism includes a delivery catheter,” or

Claim 28 – “The apparatus of claim 23 wherein said delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism includes a delivery catheter and a guide wire,” or



Claim 29 – “The apparatus of claim 23 wherein said delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism includes a delivery catheter, a guide wire having an end, and wherein said shape memory material body that comprises a shape memory polymer foam is at said end of said guide wire,” or

Claim 30 – “The apparatus of claim 23 wherein said activation system for providing said shape memory material body means with a primary shape and a secondary shape comprises radiology,” or

Claim 31 – “The apparatus of claim 23 wherein said activation system for providing said shape memory material polymer body means with a primary shape and a secondary shape comprises electromagnetic energy,” or

Claim 32 – “The apparatus of claim 23 wherein said activation system for providing said shape memory material body means with a primary shape and a secondary shape comprises electromagnetic energy delivered optically,” or

Claim 33 – “The apparatus of claim 23 wherein said shape memory polymer material body that comprises a shape memory polymer foam is a collapsed shape memory polymer foam device connected at the end of a guide wire,” or

Claim 34 – “The apparatus of claim 23 wherein said activation system for providing said shape memory polymer material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a system for optical heating using optic fibers to transport light energy to said shape memory material body that comprises a shape memory polymer foam,” or

Claim 35 – “The apparatus of claim 23 wherein said activation system for providing said shape memory polymer material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a laser and an optical fiber wherein said laser transmits laser light through said optical fiber,” or

Claim 36 – “The apparatus of claim 23 wherein said activation system for providing said shape memory polymer material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a laser and an optical fiber wherein said laser transmits laser light through a multimode optical fiber,” or

Claim 37 – “The apparatus of claim 23 wherein said activation system for providing said shape polymer memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a light absorbing material,” or

Claim 43 – “The apparatus of claim 23 wherein said shape memory material body that comprises a shape memory polymer foam comprises a shape memory polymer body with a secondary shape for being positioned in the interior of the aneurism and a larger primary shape for occluding the aneurism,” or

Claim 44 – “The apparatus of claim 23 wherein said shape memory material body that comprises a shape memory polymer foam comprises a shape memory polymer foam body having a secondary shape for being positioned in the interior of the aneurism and a larger primary shape for occluding the aneurism.”

Since the limitations listed and described above are not shown by the Maitland or Bleys references, a *prima facie* case of obviousness has not been established. Further, since the Maitland and Bleys references fail to show the claim limitations of Applicants’ claims 1, 3, 4, 6-15, 21-23, 25-37, 43, and 44 there can be no combination of the two references that would show Appellants’ claimed invention. There is no combination of the Maitland and Bleys references that would produce the combination of elements of Appellants’ claims 1, 3, 4, 6-15, 21-23, 25-37, 43, and 44. Thus, the combination of references in the Final Rejection fails to support a rejection of claims 1, 3, 4, 6-15, 21-23, 25-37, 43, and 44 under 35 U.S.C. § 103(a), and the rejection should be reversed.

#### No Reasons for Combining Maitland and Bleys

The criteria that the Examiner must provide reasons for combining the references has not been established. The Examiner must follow the “Examination Guidelines for Determining Obviousness in Light of the Supreme Court’s *KSR v. Teleflex Decision*” published October 10, 2007. These guidelines include the

requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

The Final Rejection does not provide an explanation of how or why the Maitland and Bleys references would be combined. Even if the Maitland and Bleys references were combined it still would not produce the invention of Appellants' claims 1, 3, 4, 6-15, 21-23, 25-37, 43, and 44. Thus, the combination of references in the Final Rejection fails to support a rejection of claims 1, 3, 4, 6-15, 21-23, 25-37, 43, and 44 under 35 U.S.C. § 103(a), and the rejection should be reversed.

#### No Reasonable Expectation of Success with Proposed Combination

The Final Rejection does not provide an explanation of how or why combining Maitland and Bleys would have a reasonable expectation of success. Any conceivable combination of Maitland and Bleys would not produce the invention of Appellants' claims 1, 3, 4, 6-15, 21-23, 25-37, 43, and 44. Thus, the combination of references in the Final Rejection fails to support a rejection of claims 1, 3, 4, 6-15, 21-23, 25-37, 43, and 44 under 35 U.S.C. § 103(a), and the rejection should be reversed.

#### Argument Relating to the Grounds of Rejection #2

Claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47, and 49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamiya et al. (hereinafter Kamiya) in view of Bleys et al. (hereinafter Bleys) in Grounds of Rejection #2.

#### Prima Facie Case of Obviousness Has Not Been Established

The rejection of claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47, and 49 as being obvious over Kamiya in view of Bleys in Grounds of Rejection #2 does not establish a Prima Facie case of obviousness. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for

establishing a background for determining obviousness under 35 U.S.C. § 103(a) include, "Ascertaining the differences between the prior art and the claims at issue." The Examiner bears the initial burden of factually supporting a prima facie conclusion of obviousness (M.P.E.P. Section 2142). Three basic criteria must be met in order for the Examiner to establish a prima facie case of obviousness. The prior art reference (or reference when combined) must teach or suggest all the claim limitations. There must be a reasonable expectation of success with the proposed combination. The Examiner must follow the "Examination Guidelines for Determining Obviousness in Light of the Supreme Court's KSR v. Teleflex Decision" published October 10, 2007. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

#### The Kamiya and Bleys References Do Not Teach All Claim Limitations

The criteria that prior art reference, or references when combined, must teach or suggest all the claim limitations has not been met. The Kamiya and Bleys references fail to teach many of Applicants' claim limitations. The Bleys reference is described above.

#### The Kamiya Reference

The Kamiya reference device is "a closing plug for therapeutic use within a body duct or defect." The Kamiya reference device is illustrated in FIG. 1 and described in the Kamiya reference specification reproduced below.

F I G. 1



FIG. 1 shown the basic shape of the closing plug, which as two flanges, 1, 2 of different size, being fixed at both ends of a cylindrical member 30.

The flanges 1, 2 of FIG. 1 are folded inward or outward so that they have a decreased size. After the closing plug is inserted into the defect (i.e., an opening in a body part, the opening having a rim or peripheral edge defining a boundary of the opening), the flanges restore to their original shape as shown in FIG. 1, fix the closing plug to the defect and hold it from both sides of the wall of the body part and, at the same time, the passage of the fluid through the defect stops.

Another shape of the closing plug has a narrow hole along the axis of the cylinder 30, and the size of the hole is wide enough to have a guide wire passed through and slid smoothly. A guide wire can be passed through the hole and the insertion can be facilitated.

The Kamiya reference states, "The above described object can be achieved according to the present invention by utilizing:

1. A closing plug which has a flange at least at one end thereof and which is made of a shape memory polymer having a shape recovery temperature in the range from 20° C. to 70° C.;

2. A closing plug which has two flanges, one at each end, and which is made of a shape memory polymer having a shape recovery temperature in the range of 20° C. to 70° C.;

3. A closing plug device which comprises:

- (A) a closing plug which is made of a shape memory polymer having a memory recovery temperature in the range from 20° C. to 70. degree. C., and which has a flange at least at one end and a narrow hole through which a guide wire is passed;

- (B) a guide wire which passes through the narrow hole of the closing plug so that said plug can slide over the wire; and

- (C) a pushing catheter which has an inner diameter smaller than that of the closing plug which is shaped in a decreased size before the recovery of the original shape; and

4. A closing plug device which comprises:

- (A) a closing plug which is made of a shape memory polymer having a memory recovery temperature in the range from 20° C. to 70. degree. C. and which has a flange at least at one end;

(B) a catheter which has an inner diameter larger than the maximum diameter of the closing plug and which is shaped in a decreased size before the recovery of the original shape; and

(C) a pushing wire which slides through the inside of the catheter.”

#### Kamiya and Bleys Do Not Teach Many of Appellants’ Claim Limitations

The Kamiya and Bleys references do not teach many of Applicants’ claim limitations. The missing limitations are important because the Kamiya reference device would not work with Appellants’ claimed shape memory polymer foam.

The Kamiya reference device has a flange at least at one end which is made of a shape memory polymer. Appellants’ claims on appeal require a shape memory polymer foam. The Kamiya reference device flange could not be made of a shape memory polymer foam. The shape memory polymer foam would not operate as a flange and the Kamiya reference device would not form the closing plug that is the subject of the Kamiya reference.

The Kamiya reference device also has a narrow hole through which a guide wire is passed. Appellants’ claims on appeal require a shape memory polymer foam. The Kamiya reference device could not be made of a shape memory polymer foam because the shape memory polymer foam would not provide or support a narrow hole through which a guide wire is passed.

The Kamiya and Bleys references do not teach the limitations of Applicants’ claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47, and 49 identified below.

Claim 1 – “a shape memory material body for positioning in the interior of the physical anomaly, wherein said shape memory material body comprises a shape memory polymer foam,” or

Claim 1 – “a delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly,” or

Claim 1 – “a system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape for

occluding the physical anomaly and a secondary shape for being delivered into the interior of the physical anomaly," or

Claim 3- "The apparatus of claim 1 wherein said shape memory polymer foam is a shape memory polymer foam with an open cell foam structure that has an expansion ratio in the range of 200 percent to 20000 percent," or

Claim 7 - "The apparatus of claim 1 wherein said delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly includes a delivery catheter, a guide wire having an end, and wherein said shape memory material body that comprises a shape memory polymer foam is at said end of said guide wire," or

Claim 21 - "The apparatus of claim 1 wherein said shape memory material body that comprises a shape memory polymer foam comprises a shape memory polymer body that comprises a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly," or

Claim 22 - "The apparatus of claim 1 wherein said shape memory material body that comprises a shape memory polymer foam comprises a shape memory polymer foam body having a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly," or

Claim 23 - "An apparatus for endovascular therapy by occluding an aneurism having an interior," or

Claim 23 - "shape memory polymer material body for being positioned in the interior of the aneurism, wherein said shape memory polymer material body comprises a shape memory polymer foam," or

Claim 23 - "a delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism," or

Claim 23 - "an activation system for providing said shape memory polymer material body with a primary shape for occluding the aneurism and a secondary shape for being positioned in the interior of the aneurism," or

Claim 25 - "The apparatus of claim 23 wherein said shape memory polymer material body that comprises a shape memory polymer foam is a shape

memory polymer foam with an open cell foam structure that has an expansion ratio in the range of 200 percent to 20000 percent," or

Claim 27 – "The apparatus of claim 23 wherein said delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism includes a delivery catheter," or

Claim 28 – "The apparatus of claim 23 wherein said delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism includes a delivery catheter and a guide wire," or

Claim 29 – "The apparatus of claim 23 wherein said delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism includes a delivery catheter, a guide wire having an end, and wherein said shape memory material body that comprises a shape memory polymer foam is at said end of said guide wire," or

Claim 43 – "The apparatus of claim 23 wherein said shape memory material body that comprises a shape memory polymer foam comprises a shape memory polymer body with a secondary shape for being positioned in the interior of the aneurism and a larger primary shape for occluding the aneurism," or

Claim 44 – "The apparatus of claim 23 wherein said shape memory material body that comprises a shape memory polymer foam comprises a shape memory polymer foam body having a secondary shape for being positioned in the interior of the aneurism and a larger primary shape for occluding the aneurism," or

Claim 45 – "providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly," or

Claim 45 – "positioning said shape memory polymer material body comprising a shape memory polymer foam in the interior of the physical anomaly when said shape memory polymer material body is in said secondary shape," or



Claim 45 – “causing said shape memory polymer material body comprising a shape memory polymer foam to change to said larger primary shape for occluding the anomaly,” or

Claim 47 – “The method of claim 45 wherein said step of positioning said shape memory polymer material body comprising a shape memory polymer foam in the interior of the physical anomaly when said shape memory polymer material body comprising a shape memory polymer foam is in said secondary shape is accomplished using a catheter,” or

Claim 49 – “The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using a collapsed shape memory polymer foam device connected at the end of a guide wire.”

Since the limitations listed and described above are not shown by the Kamiya or Bleys references, a prima facie case of obviousness has not been established. Further, since the Kamiya and Bleys references fail to show the claim limitations of Applicants’ claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47, and 49 there can be no combination of the two references that would show Appellants’ claimed invention. There is no combination of the Kamiya and Bleys references that would produce the combination of elements of Appellants’ claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47, and 49. Thus, the combination of references in the Final Rejection fails to support a rejection of claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47, and 49 under 35 U.S.C. § 103(a), and the rejection should be reversed.

#### No Reasons for Combining Kamiya and Bleys

The criteria that the Examiner must provide reasons for combining the references has not been established. The Examiner must follow the “Examination Guidelines for Determining Obviousness in Light of the Supreme Court’s KSR v. Teleflex Decision” published October 10, 2007. These guidelines include the

requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

The Final Rejection does not provide an explanation of how or why the Kamiya and Bleys references would be combined. Even if the Kamiya and Bleys references were combined it still would not produce the invention of Appellants' claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47, and 49. The Kamiya reference device has a flange at least at one end which is made of a shape memory polymer. Appellants' claims on appeal require a shape memory polymer foam. The Kamiya reference device flange could not be made of a shape memory polymer foam. The shape memory polymer foam would not operate as a flange and the Kamiya reference device would not form the closing plug that is the subject of the Kamiya reference.

The Kamiya reference device also has a narrow hole through which a guide wire is passed. Appellants' claims on appeal require a shape memory polymer foam. The Kamiya reference device could not be made of a shape memory polymer foam because the shape memory polymer foam would not provide or support a narrow hole through which a guide wire is passed.

Thus, the combination of references in the Final Rejection fails to support a rejection of claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47, and 49 under 35 U.S.C. § 103(a), and the rejection should be reversed.

#### No Reasonable Expectation of Success with Proposed Combination

The Final Rejection does not provide an explanation of how or why combining Kamiya and Bleys would have a reasonable expectation of success. The Kamiya reference device has a flange at least at one end which is made of a shape memory polymer. Appellants' claims on appeal require a shape memory polymer foam. The Kamiya reference device flange could not be made of a shape memory polymer foam. The shape memory polymer foam would not

operate as a flange and the Kamiya reference device would not form the closing plug that is the subject of the Kamiya reference.

The Kamiya reference device also has a narrow hole through which a guide wire is passed. Appellants' claims on appeal require a shape memory polymer foam. The Kamiya reference device could not be made of a shape memory polymer foam because the shape memory polymer foam would not provide or support a narrow hole through which a guide wire is passed.

Any conceivable combination of Kamiya and Bleys would not produce the invention of Appellants' claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47, and 49. Thus, the combination of references in the Final Rejection fails to support a rejection of claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47, and 49 under 35 U.S.C. § 103(a), and the rejection should be reversed.

### **Argument Relating to the Grounds of Rejection #3**

Claims 2 and 24 were rejected under 35 U.S.C. § 103(a) as being obvious over Maitland in view of Bleys and further in view of Picha (US 5,207,709) in Grounds of Rejection #3. The Maitland and Bleys references are described above.

#### **The Picha Reference**

The Picha reference "relates generally to implantable medical devices and, more particularly, to an improved textured exterior surface thereon having fin projections." The Picha reference is illustrated in FIG. 1 and described in the portions of the specification reproduced below.

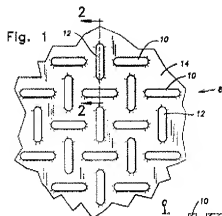


FIG. 1 illustrates a portion of an implant 8 having a surface morphology in accordance with the present invention. The implant has a supporting structure which has an outer surface 14. Projecting outwardly from the outer surface are fin projections or fins 10, 12. The fins are shown as being of relatively uniform size and shape and regularly arrayed and are shown as generally the same except for their axial orientation on the outer surface of the implant. The fins need not be of relatively uniform size or shape or regularly arrayed. They may be irregularly or randomly arrayed. As can be seen, the fins are separate and distinct from each other and unconnected. That is, they stand alone and are not joined with each other to form walls, polygonal structures, etc. The fins may extend over less than all of the outer surface area of the supporting structure to form a textured exterior surface; they may also extend over substantially all of it. In FIG. 1, the fins are arrayed in a basket weave-like arrangement or pattern on the outer surface of the implant. Basket weave-like pattern, as used in the claims, means this type of arrangement. This arrangement will disrupt long-range ordering of collagen formation in the fibrous capsule surrounding the implant. The collagen will form next to the surface of the implant between and among the fin projections. The collagen will be forced to form along sinuous, serpentine, wavy, twisting paths, leading to crooked, nonparallel, less strong bundles of collagen fibers. A path is sinuous when it is crooked, constantly changes direction, is twisting, wavy, serpentine, etc. The textured surface of

the present invention is characterized by the absence of straight line paths over a significant portion of the textured surface.

#### Prima Facie Case of Obviousness Has Not Been Established

The rejection of claims 2 and 24 as being obvious over Maitland in view of Bleys in Grounds of Rejection #3 does not establish a *Prima Facie* case of obviousness. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) include, “Ascertaining the differences between the prior art and the claims at issue.” The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). Three basic criteria must be met in order for the Examiner to establish a *prima facie* case of obviousness. The prior art reference (or reference when combined) must teach or suggest all the claim limitations. There must be a reasonable expectation of success with the proposed combination. The Examiner must follow the “Examination Guidelines for Determining Obviousness in Light of the Supreme Court’s *KSR v. Teleflex* Decision” published October 10, 2007. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

#### Maitland, Bleys, and Picha Do Not Teach All Claim Limitations

The criteria that prior art reference, or references when combined, must teach or suggest all the claim limitations has not been met. The Maitland and Bleys and Picha references fail to teach most of Applicants’ claim limitations. The Maitland and Bleys and Picha references do not teach the limitations of Applicants’ claims 2 and 24 identified below.

Parent Claim 1 – “An apparatus for endovascular therapy by occluding a physical anomaly, said anomaly having an interior,” or

Parent Claim 1 – “a shape memory material body for positioning in the interior of the physical anomaly, wherein said shape memory material body comprises a shape memory polymer foam,” or

Parent Claim 1 – “a delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly,” or

Parent Claim 1 – “a system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape for occluding the physical anomaly and a secondary shape for being delivered into the interior of the physical anomaly,” or

Claim 2 – “The apparatus of claim 1 wherein said shape memory polymer foam is a shape memory polymer foam with an open cell foam structure that has pores and wherein said pores have a mean pore size between ten microns and fifty microns,” or

Parent Claim 23 – “An apparatus for endovascular therapy by occluding an aneurism having an interior,” or

Parent Claim 23 – “shape memory polymer material body for being positioned in the interior of the aneurism, wherein said shape memory polymer material body comprises a shape memory polymer foam,” or

Parent Claim 23 – “a delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism,” or

Parent Claim 23 – “an activation system for providing said shape memory polymer material body with a primary shape for occluding the aneurism and a secondary shape for being positioned in the interior of the aneurism,” or

Claim 24 – “The apparatus of claim 23 wherein said shape memory polymer material body that comprises a shape memory polymer foam is a shape memory polymer foam with an open cell foam structure that has an expansion ratio in the range of 200 percent to 20000 percent.”

Since the limitations listed and described above are not shown by the Maitland or Bleys or Picha references, a *prima facie* case of obviousness has not been established. Further, since the Maitland and Bleys and Picha references

fail to show the claim limitations of Applicants' claims 2 and 24 there can be no combination of the three references that would show Appellants' claimed invention. There is no combination of the Maitland and Bleys and Picha references that would produce the combination of elements of Appellants' claims 2 and 24. Thus, the combination of references in the Final Rejection fails to support a rejection of claims 2 and 24 under 35 U.S.C. § 103(a), and the rejection should be reversed.

No Reasons for Combining Maitland and Bleys and Picha

The criteria that the Examiner must provide reasons for combining the references has not been established. The Examiner must follow the "Examination Guidelines for Determining Obviousness in Light of the Supreme Court's KSR v. Teleflex Decision" published October 10, 2007. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

The Final Rejection does not provide an explanation of how or why the Maitland and Bleys and Picha references would be combined. Even if the Maitland and Bleys and Picha references were combined it still would not produce the invention of Appellants' claims 2 and 24. Thus, the combination of references in the Final Rejection fails to support a rejection of claims 2 and 24 under 35 U.S.C. § 103(a), and the rejection should be reversed.

No Reasonable Expectation of Success with Proposed Combination

The Final Rejection does not provide an explanation of how or why combining Maitland and Bleys and Picha would have a reasonable expectation of success. Any conceivable combination of Maitland and Bleys and Picha would not produce the invention of Appellants' claims 2 and 24. Thus, the combination of references in the Final Rejection fails to support a

rejection of claims 2 and 24 under 35 U.S.C. § 103(a), and the rejection should be reversed.

#### **Argument Relating to the Grounds of Rejection #4**

Claims 2, 24, and 46 were rejected under 35 U.S.C. § 103(a) as being obvious over Kamiya in view of Bleys and further in view of Picha in Grounds of Rejection #4. The Kamiya, Bleys, and Picha references are described above.

#### **Prima Facie Case of Obviousness Has Not Been Established**

The rejection of claims 2, 24, and 46 as being obvious over Kamiya in view of Bleys in Grounds of Rejection #4 does not establish a *Prima Facie* case of obviousness. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) include, “Ascertaining the differences between the prior art and the claims at issue.” The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). Three basic criteria must be met in order for the Examiner to establish a *prima facie* case of obviousness. The prior art reference (or reference when combined) must teach or suggest all the claim limitations. There must be a reasonable expectation of success with the proposed combination. The Examiner must follow the “Examination Guidelines for Determining Obviousness in Light of the Supreme Court’s *KSR v. Teleflex Decision*” published October 10, 2007. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination.



### Kamiya, Bleys, and Picha Do Not Teach All Claim Limitations

The criteria that prior art reference, or references when combined, must teach or suggest all the claim limitations has not been met. The Kamiya and Bleys and Picha references fail to teach most of Applicants' claim limitations. The Kamiya and Bleys and Picha references do not teach the limitations of Applicants' claims 2, 24, and 46 identified below.

Parent Claim 1 – “a shape memory material body for positioning in the interior of the physical anomaly, wherein said shape memory material body comprises a shape memory polymer foam,” or

Parent Claim 1 – “a delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly,” or

Parent Claim 1 – “a system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape for occluding the physical anomaly and a secondary shape for being delivered into the interior of the physical anomaly,” or

Claim 2 – “The apparatus of claim 1 wherein said shape memory polymer foam is a shape memory polymer foam with an open cell foam structure that has pores and wherein said pores have a mean pore size between ten microns and fifty microns,” or

Parent Claim 23 – “An apparatus for endovascular therapy by occluding an aneurism having an interior,” or

Parent Claim 23 – “shape memory polymer material body for being positioned in the interior of the aneurism, wherein said shape memory polymer material body comprises a shape memory polymer foam,” or

Parent Claim 23 – “a delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism,” or

Parent Claim 23 – “an activation system for providing said shape memory polymer material body with a primary shape for occluding the aneurism and a secondary shape for being positioned in the interior of the aneurism,” or

Claim 24 – “The apparatus of claim 23 wherein said shape memory polymer material body that comprises a shape memory polymer foam is a shape memory polymer foam with an open cell foam structure that has an expansion ratio in the range of 200 percent to 20000 percent.”

Parent Claim 45 – “providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly,” or

Parent Claim 45 – “positioning said shape memory polymer material body comprising a shape memory polymer foam in the interior of the physical anomaly when said shape memory polymer material body is in said secondary shape, and causing said shape memory polymer material body comprising a shape memory polymer foam to change to said larger primary shape for occluding the anomaly,” or

Claim 46 – “The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises providing a shape memory polymer foam body with an open cell foam structure that has pores and wherein said pores have a mean pore size between ten microns and fifty microns with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly.”

Since the limitations listed and described above are not shown by the Kamiya or Bleys or Picha references, a *prima facie* case of obviousness has not been established. Further, since the Kamiya and Bleys and Picha references fail to show the claim limitations of Applicants' claims 2, 24, and 46 there can be no combination of the three references that would show Appellants' claimed invention. There is no combination of the Kamiya and Bleys and Picha references that would produce the combination of elements of Appellants' claims 2, 24, and 46. Thus, the combination of references in the Final Rejection fails to

support a rejection of claims 2, 24, and 46 under 35 U.S.C. § 103(a), and the rejection should be reversed.

#### **No Reasons for Combining Kamiya and Bleys and Picha**

The criteria that the Examiner must provide reasons for combining the references has not been established. The Examiner must follow the “Examination Guidelines for Determining Obviousness in Light of the Supreme Court’s KSR v. Teleflex Decision” published October 10, 2007. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

The Final Rejection does not provide an explanation of how or why the Kamiya and Bleys and Picha references would be combined. Even if the Kamiya and Bleys and Picha references were combined it still would not produce the invention of Appellants’ claims 2, 24, and 46. Thus, the combination of references in the Final Rejection fails to support a rejection of claims 2, 24, and 46 under 35 U.S.C. § 103(a), and the rejection should be reversed.

#### **No Reasonable Expectation of Success with Proposed Combination**

The Final Rejection does not provide an explanation of how or why combining Kamiya and Bleys and Picha would have a reasonable expectation of success. Any conceivable combination of Kamiya and Bleys and Picha would not produce the invention of Appellants’ claims 2, 24, and 46. Thus, the combination of references in the Final Rejection fails to support a rejection of claims 2, 24, and 46 under 35 U.S.C. § 103(a), and the rejection should be reversed.

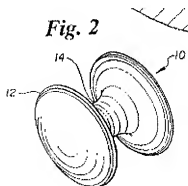
#### **Argument Relating to the Grounds of Rejection #5**

Claim 5 was rejected under 35 U.S.C. § 103(a) as being obvious over Kamiya in view of Bleys and further in view of Linden et al (Hereinafter Linden)

in Grounds of Rejection #5. The Kamiya and Bleys references are described above.

### The Linden Reference

The Linden reference is illustrated in FIG. 2 and described in the portions of the specification reproduced below.



As shown in FIG. 2, a device of the invention shown generally at 10 in one embodiment, is a preshaped plug 12 in the form of a disc with a narrower center portion 14. In this form, the device 10 serves as a plug 12 which is inserted into a tissue defect such as a septal defect. The polymeric material in this embodiment is ideally a polymeric self-hardening foam or sponge material which is soft and easily deformable so that it can be readily plugged into the defect.

In its deliverable form, plug 12 would preferably be bathed or presoaked in an organic solution or aqueous solution of a specific pH or ionic concentration. This is because the mechanism of hardening in this case resides with the transition or replacement of one fluid for another. For instance, a solution of water and DMSO (dimethylsulfoxide) at a specific pH would keep the polymer soft and contracted. Once the fluid is replaced by a second fluid at a different pH probably near physiological pH, or in contact with blood, the polymer expands and hardens. There may be three phases to the phase change, governed by the fluid contacting the polymer: 1) soft and contracted; 2) soft and expanded; and 3) hard and expanded. This would be accomplished by a ternary system of fluid that modifies both pH and ionic strength or hydrophilicity, all of which would be delivered to the plug in-situ via the catheter.

Polymers that would alter their modulus through a change in pH include acid soluble collagen or poly-L-lysine which precipitates above a pH of 3. 0. Polymers such as low molecular weight poly-L-lactic acid are soluble in DMSO

and would precipitate on replacing the water miscible DMSO with water or saline solutions.

#### Prima Facie Case of Obviousness Has Not Been Established

The rejection of claim 5 as being obvious over Kamiya in view of Bleys in Grounds of Rejection #5 does not establish a *Prima Facie* case of obviousness. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) include, "Ascertaining the differences between the prior art and the claims at issue." The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). Three basic criteria must be met in order for the Examiner to establish a *prima facie* case of obviousness. The prior art reference (or reference when combined) must teach or suggest all the claim limitations. There must be a reasonable expectation of success with the proposed combination. The Examiner must follow the "Examination Guidelines for Determining Obviousness in Light of the Supreme Court's *KSR v. Teleflex Decision*" published October 10, 2007. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

#### Kamiya, Bleys, and Linden Do Not Teach All Claim Limitations

The criteria that prior art reference, or references when combined, must teach or suggest all the claim limitations has not been met. The Kamiya and Bleys and Linden references fail to teach most of Applicants' claim limitations. The Kamiya and Bleys and Linden references do not teach the limitations of Applicants' claim 5 identified below.

Parent Claim 1 – "a shape memory material body for positioning in the interior of the physical anomaly, wherein said shape memory material body comprises a shape memory polymer foam," or

Parent Claim 1 – “a delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly,” or

Parent Claim 1 – “a system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape for occluding the physical anomaly and a secondary shape for being delivered into the interior of the physical anomaly,” or

Claim 5 – “The apparatus of claim 1 wherein said shape memory polymer foam is a shape memory foam with an open cell foam structure that is composed of a polyurethane shape memory polymer having a ten percent solution of shape memory polymer in dimethyl sulfoxide.

Since the limitations listed and described above are not shown by the Kamiya or Bleys or Linden references, a *prima facie* case of obviousness has not been established. Further, since the Kamiya and Bleys and Linden references fail to show the claim limitations of Applicants’ claim 5 there can be no combination of the three references that would show Appellants’ claimed invention. There is no combination of the Kamiya and Bleys and Linden references that would produce the combination of elements of Appellants’ claim 5. Thus, the combination of references in the Final Rejection fails to support a rejection of claim 5 under 35 U.S.C. § 103(a), and the rejection should be reversed.

#### No Reasons for Combining Kamiya and Bleys and Linden

The criteria that the Examiner must provide reasons for combining the references has not been established. The Examiner must follow the “Examination Guidelines for Determining Obviousness in Light of the Supreme Court’s KSR v. Teleflex Decision” published October 10, 2007. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

The Final Rejection does not provide an explanation of how or why the Kamiya and Bleys and Linden references would be combined. Even if the

Kamiya and Bleys and Linden references were combined it still would not produce the invention of Appellants' claim 5. Thus, the combination of references in the Final Rejection fails to support a rejection of claim 5 under 35 U.S.C. § 103(a), and the rejection should be reversed.

No Reasonable Expectation of Success with Proposed Combination

The Final Rejection does not provide an explanation of how or why combining Kamiya and Bleys and Linden would have a reasonable expectation of success. Any conceivable combination of Kamiya and Bleys and Linden would not produce the invention of Appellants' claim 5. Thus, the combination of references in the Final Rejection fails to support a rejection of claim 5 under 35 U.S.C. § 103(a), and the rejection should be reversed.

Argument Relating to the Grounds of Rejection #6

Claims 17-20 and 39-42 were rejected under 35 U.S.C. § 103(a) as being obvious over Kamiya or Maitland in view of Bleys and further in view of Porter (US 2002/0165582) in Grounds of Rejection #6. The Kamiya, Maitland, and Bleys references are described above.

The Porter Reference

The Porter reference is illustrated in FIG. 1 and described in the portions of the specification reproduced below.

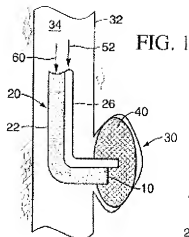


FIG. 1 illustrates one embodiment with a catheter delivering a first material and a second material. Catheter [20] has two channels, the first channel [22] carries the first material [60] and the second channel to carry the second material [26] to the vascular site [30] in the blood vessel [32]. The prepolymer [40] coming out of the catheter tip [10] fills the vascular site [30]. The second material [26] is positioned near the catheter tip [10]. During delivery of the prepolymer [40], the blood flow [34] is not obstructed by the catheter [20]. The second material [52] flows through second channel [26] to activate the prepolymer [40] to activate the prepolymer [40] coming out of catheter tip [10]. Once the prepolymer [40] at least partially polymerizes, the catheter [20] can then be removed from the blood vessel [32]. The vascular site [30] is then embolized.

#### Prima Facie Case of Obviousness Has Not Been Established

The rejection of claims 17-20 and 39-42 as being obvious over Kamiya, Maitland, Bleys, and Porter in Grounds of Rejection #6 does not establish a *Prima Facie* case of obviousness. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) include, "Ascertaining the differences between the prior art and the claims at issue." The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). Three basic criteria must be met in order for the Examiner to establish a *prima facie* case of obviousness. The prior art reference (or reference when combined) must teach or suggest all the claim



limitations. There must be a reasonable expectation of success with the proposed combination. The Examiner must follow the “Examination Guidelines for Determining Obviousness in Light of the Supreme Court’s KSR v. Teleflex Decision” published October 10, 2007. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

Kamiya, Maitland, Bleys, and Porter Do Not Teach Claim Limitations

The criteria that prior art reference, or references when combined, must teach or suggest all the claim limitations has not been met. The Kamiya, Maitland, Bleys, and Porter references fail to teach most of Applicants’ claim limitations. The Kamiya, Maitland, Bleys, and Porter references do not teach the limitations of Applicants’ claims 17-20 and 39-42 identified below.

Parent Claim 1 – “a shape memory material body for positioning in the interior of the physical anomaly, wherein said shape memory material body comprises a shape memory polymer foam,” or

Parent Claim 1 – “a delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly,” or

Parent Claim 1 – “a system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape for occluding the physical anomaly and a secondary shape for being delivered into the interior of the physical anomaly,” or

Claim 17 – “The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises microparticles that convert RF radiation to heat,” or

Claim 18 – “The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises microparticles of a material which can selectively absorb RF radiation converting it to heat,” or

Claim 19 – “The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises nanoparticles that convert RF radiation to heat,” or

Claim 20 – “The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises nanoparticles of a material which can selectively absorb RF radiation converting it to heat,” or

Parent Claim 23 – “An apparatus for endovascular therapy by occluding an aneurism having an interior,” or

Parent Claim 23 – “shape memory polymer material body for being positioned in the interior of the aneurism, wherein said shape memory polymer material body comprises a shape memory polymer foam,” or

Parent Claim 23 – “a delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism,” or

Parent Claim 23 – “an activation system for providing said shape memory polymer material body with a primary shape for occluding the aneurism and a secondary shape for being positioned in the interior of the aneurism,” or

Claim 39 – “The apparatus of claim 23 wherein said activation system for providing said shape memory polymer material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises microparticles that convert RF radiation to heat,” or

Claim 40 – “The apparatus of claim 23 wherein said activation system for providing said shape memory polymer material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises microparticles of a material which can selectively absorb RF radiation converting it to heat,” or

Claim 41 – “The apparatus of claim 23 wherein said activation system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises nanoparticles that convert RF radiation to heat,” or

Claim 42 – “The apparatus of claim 23 wherein said activation system for providing said shape memory material body that comprises a shape memory

polymer foam with a primary shape and a secondary shape comprises nanoparticles of a material which can selectively absorb RF radiation converting it to heat.”

Since the limitations listed and described above are not shown by the Kamiya, Maitland, Bleys, or Porter references, a *prima facie* case of obviousness has not been established. Further, since the Kamiya, Maitland, Bleys, and Porter references fail to show the claim limitations of Applicants’ claims 17-20 and 39-42 there can be no combination of the four references that would show Appellants’ claimed invention. There is no combination of the Kamiya, Maitland, Bleys, and Porter references that would produce the combination of elements of Appellants’ claims 17-20 and 39-42. Thus, the combination of references in the Final Rejection fails to support a rejection of claims 17-20 and 39-42 under 35 U.S.C. § 103(a), and the rejection should be reversed.

#### No Reasons for Combining Kamiya, Maitland, Bleys, and Porter

The criteria that the Examiner must provide reasons for combining the references has not been established. The Examiner must follow the “Examination Guidelines for Determining Obviousness in Light of the Supreme Court’s KSR v. Teleflex Decision” published October 10, 2007. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

The Final Rejection does not provide an explanation of how or why the Kamiya, Maitland, Bleys, and Porter references would be combined. Even if the Kamiya, Maitland, Bleys, and Porter references were combined it still would not produce the invention of Appellants’ claims 17-20 and 39-42. Thus, the combination of references in the Final Rejection fails to support a rejection of claims 17-20 and 39-42 under 35 U.S.C. § 103(a), and the rejection should be reversed.

### No Reasonable Expectation of Success with Proposed Combination

The Final Rejection does not provide an explanation of how or why combining Kamiya, Maitland, Bleys, and Porter would have a reasonable expectation of success. Any conceivable combination of Kamiya, Maitland, Bleys, and Porter would not produce the invention of Appellants' claims 17-20 and 39-42. Thus, the combination of references in the Final Rejection fails to support a rejection of claims 17-20 and 39-42 under 35 U.S.C. § 103(a), and the rejection should be reversed.

### Argument Relating to the Grounds of Rejection #7

Claims 48 and 50-52 were rejected under 35 U.S.C. § 103(a) as being obvious over Kamiya in view of Bleys and further in view of Maitland in Grounds of Rejection #7. The Kamiya, Bleys, and Maitland references are described above.

### Prima Facie Case of Obviousness Has Not Been Established

The rejection of claims 48 and 50-52 as being obvious over Kamiya, Bleys, and Maitland in Grounds of Rejection #7 does not establish a *Prima Facie* case of obviousness. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) include, "Ascertaining the differences between the prior art and the claims at issue." The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). Three basic criteria must be met in order for the Examiner to establish a *prima facie* case of obviousness. The prior art reference (or reference when combined) must teach or suggest all the claim limitations. There must be a reasonable expectation of success with the proposed combination. The Examiner must follow the "Examination Guidelines for Determining

Obviousness in Light of the Supreme Court's KSR v. Teleflex Decision" published October 10, 2007. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

Kamiya, Bleys, and Maitland Do Not Teach All Claim Limitations

The criteria that prior art reference, or references when combined, must teach or suggest all the claim limitations has not been met. The Kamiya, Bleys, and Maitland references fail to teach most of Applicants' claim limitations. The Kamiya, Bleys, and Maitland references do not teach the limitations of Applicants' claims 48 and 50-52 identified below.

Parent claim 45 – "providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly," or

Parent claim 45 – "positioning said shape memory polymer material body comprising a shape memory polymer foam in the interior of the physical anomaly when said shape memory polymer material body is in said secondary shape," or

Parent claim 45 – "causing said shape memory polymer material body comprising a shape memory polymer foam to change to said larger primary shape for occluding the anomaly," or

Claim 48 – "The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises delivering electromagnetic energy optically to said shape memory polymer material body comprising a shape memory polymer foam," or

Claim 50 – "The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for

occluding the anomaly comprises optical heating said shape memory polymer material body comprising a shape memory polymer foam,” or

Claim 51 – “The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises optical heating said shape memory polymer material body comprising a shape memory polymer foam through optic fibers,” or

Claim 52 – “The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using a laser and an optical fiber to transmit laser light through said optical fiber.”

Since the limitations listed and described above are not shown by the Kamiya, Bleys, or Maitland references, a *prima facie* case of obviousness has not been established. Further, since the Kamiya, Bleys, and Maitland references fail to show the claim limitations of Applicants’ claims 48 and 50-52 there can be no combination of the three references that would show Appellants’ claimed invention. There is no combination of the Kamiya, Bleys, and Maitland references that would produce the combination of elements of Appellants’ claims 48 and 50-52. Thus, the combination of references in the Final Rejection fails to support a rejection of claims 48 and 50-52 under 35 U.S.C. § 103(a), and the rejection should be reversed.

#### No Reasons for Combining Kamiya and Bleys and Maitland

The criteria that the Examiner must provide reasons for combining the references has not been established. The Examiner must follow the “Examination Guidelines for Determining Obviousness in Light of the Supreme Court’s KSR v. Teleflex Decision” published October 10, 2007. These guidelines include the

requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

The Final Rejection does not provide an explanation of how or why the Kamiya, Bleys, and Maitland references would be combined. Even if the Kamiya, Bleys, and Maitland references were combined it still would not produce the invention of Appellants' claims 48 and 50-52. Thus, the combination of references in the Final Rejection fails to support a rejection of claims 48 and 50-52 under 35 U.S.C. § 103(a), and the rejection should be reversed.

No Reasonable Expectation of Success with Proposed Combination

The Final Rejection does not provide an explanation of how or why combining Kamiya, Bleys, and Maitland would have a reasonable expectation of success. Any conceivable combination of Kamiya, Bleys, and Maitland would not produce the invention of Appellants' claims 48 and 50-52. Thus, the combination of references in the Final Rejection fails to support a rejection of claims 48 and 50-52 under 35 U.S.C. § 103(a), and the rejection should be reversed.

Argument Relating to the Grounds of Rejection #8

Claims 53-56 were rejected under 35 U.S.C. § 103(a) as being obvious over Kamiya in view of Bleys and further in view of Porter in Grounds of Rejection #8. The Kamiya, Bleys, and Porter references are described above.

Prima Facie Case of Obviousness Has Not Been Established

The rejection of claims 53-56 as being obvious over Kamiya, Bleys, and Porter in Grounds of Rejection #8 does not establish a *Prima Facie* case of obviousness. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) include, "Ascertaining the

differences between the prior art and the claims at issue.” The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). Three basic criteria must be met in order for the Examiner to establish a *prima facie* case of obviousness. The prior art reference (or reference when combined) must teach or suggest all the claim limitations. There must be a reasonable expectation of success with the proposed combination. The Examiner must follow the “Examination Guidelines for Determining Obviousness in Light of the Supreme Court’s KSR v. Teleflex Decision” published October 10, 2007. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

Kamiya, Bleys, and Porter Do Not Teach All Claim Limitations

The criteria that prior art reference, or references when combined, must teach or suggest all the claim limitations has not been met. The Kamiya, Bleys, and Porter references fail to teach most of Applicants’ claim limitations. The Kamiya, Bleys, and Porter references do not teach the limitations of Applicants’ claims 53-56 identified below.

Parent claim 45 – “providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly,” or

Parent claim 45 – “positioning said shape memory polymer material body comprising a shape memory polymer foam in the interior of the physical anomaly when said shape memory polymer material body is in said secondary shape,” or

Parent claim 45 – “causing said shape memory polymer material body comprising a shape memory polymer foam to change to said larger primary shape for occluding the anomaly,” or



Claim 53 – “The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using microparticles that convert RF radiation to heat,” or

Claim 54 – “The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using microparticles of a material which can selectively absorb RF radiation converting it to heat,” or

Claim 55 – “The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using nanoparticles that convert RF radiation to heat,” or

Claim 56 – “The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using nanoparticles of a material which can selectively absorb RF radiation converting it to heat.”

Since the limitations listed and described above are not shown by the Kamiya, Bleys, or Porter references, a *prima facie* case of obviousness has not been established. Further, since the Kamiya, Bleys, and Porter references fail to show the claim limitations of Applicants’ claims 53-56 there can be no combination of the three references that would show Appellants’ claimed invention. There is no combination of the Kamiya, Bleys, and Porter references that would produce the combination of elements of Appellants’ claims 53-56. Thus, the combination of references in the Final Rejection fails to support a

rejection of claims 53-56 under 35 U.S.C. § 103(a), and the rejection should be reversed.

**No Reasons for Combining Kamiya and Bleys and Porter**

The criteria that the Examiner must provide reasons for combining the references has not been established. The Examiner must follow the “Examination Guidelines for Determining Obviousness in Light of the Supreme Court’s KSR v. Teleflex Decision” published October 10, 2007. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

The Final Rejection does not provide an explanation of how or why the Kamiya, Bleys, and Porter references would be combined. Even if the Kamiya, Bleys, and Porter references were combined it still would not produce the invention of Appellants’ claims 53-56. Thus, the combination of references in the Final Rejection fails to support a rejection of claims 53-56 under 35 U.S.C. § 103(a), and the rejection should be reversed.

**No Reasonable Expectation of Success with Proposed Combination**

The Final Rejection does not provide an explanation of how or why combining Kamiya, Bleys, and Porter would have a reasonable expectation of success. Any conceivable combination of Kamiya, Bleys, and Porter would not produce the invention of Appellants’ claims 53-56. Thus, the combination of references in the Final Rejection fails to support a rejection of claims 53-56 under 35 U.S.C. § 103(a), and the rejection should be reversed.

**Argument Relating to the Grounds of Rejection #9**

Claims 53-56 were rejected were rejected under 35 U.S.C. § 103(a) as being unpatentable over Maitland in Grounds of Rejection #9. The Maitland reference is described above.

### Prima Facie Case of Obviousness Has Not Been Established

The rejection of claims 53-56 as being obvious over Maitland in Grounds of Rejection #9 does not establish a *Prima Facie* case of obviousness. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) include, "Ascertaining the differences between the prior art and the claims at issue." The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). Three basic criteria must be met in order for the Examiner to establish a *prima facie* case of obviousness. The prior art reference (or reference when combined) must teach or suggest all the claim limitations. There must be a reasonable expectation of success with the proposed combination. The Examiner must follow the "Examination Guidelines for Determining Obviousness in Light of the Supreme Court's *KSR v. Teleflex Decision*" published October 10, 2007. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

### The Maitland Reference Does Not Teach All Claim Limitations

The criteria that prior art reference, or references when combined, must teach or suggest all the claim limitations has not been met. The Maitland reference fails to teach most of Applicants' claim limitations. The Maitland reference does not teach the limitations of Applicants' claims 53-56 identified below.

Parent claim 45 – "providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly," or

Parent claim 45 – "positioning said shape memory polymer material body comprising a shape memory polymer foam in the interior of the

physical anomaly when said shape memory polymer material body is in said secondary shape," or

Parent claim 45 – "causing said shape memory polymer material body comprising a shape memory polymer foam to change to said larger primary shape for occluding the anomaly," or

Claim 53 – "The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using microparticles that convert RF radiation to heat," or

Claim 54 – "The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using microparticles of a material which can selectively absorb RF radiation converting it to heat," or

Claim 55 – "The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using nanoparticles that convert RF radiation to heat," or

Claim 56 – "The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using nanoparticles of a material which can selectively absorb RF radiation converting it to heat."

Since the limitations listed and described above are not shown by the Maitland reference, a *prima facie* case of obviousness has not been established. There is no modification of the Maitland reference that would produce the combination of elements of Appellants' claims 53-56. Thus, the Final Rejection

fails to support a rejection of claims 53-56 under 35 U.S.C. § 103(a) and the rejection should be reversed.

#### No Reasons for Modifying Maitland

The criteria that the Examiner must provide reasons for modifying the references has not been established. The Examiner must follow the “Examination Guidelines for Determining Obviousness in Light of the Supreme Court’s KSR v. Teleflex Decision” published October 10, 2007. These guidelines include the requirement that the Examiner provide reasons for combining or modifying the references to produce the proposed combination.

The Final Rejection does not provide an explanation of how or why the Maitland would be modified. Even if the Maitland reference was modified it still would not produce the invention of Appellants’ claims 53-56. Thus, the Final Rejection under 35 U.S.C. § 103(a) should be reversed.

#### No Reasonable Expectation of Success with Proposed Combination

The Final Rejection does not provide an explanation of how or why modifying Maitland would have a reasonable expectation of success. Any conceivable modification of Maitland would not produce the invention of Appellants’ claims 16 and 38. Thus, the Final Rejection fails to support a rejection of claims 53-56 under 35 U.S.C. § 103(a), and the rejection should be reversed.

### SUMMARY

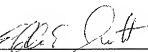
The present invention provides a system for occluding (closing up or blocking off) a physical anomaly. The references applied against Appellants’ claims 1-56 on appeal do not show the claimed system. The primary Maitland reference is a system for removing a clot in a vein or in an artery and is not a

system for closing up or blocking off a physical anomaly as claimed by Appellants in claims 1-56 on appeal.

The primary Kamiya reference device has a shape memory polymer flange at one end whereas Appellants' claims on appeal require a shape memory polymer foam. The Kamiya shape memory polymer flange could not be made of a shape memory polymer foam. The shape memory polymer foam would not operate as a flange and the Kamiya reference device would not form the closing plug that is the subject of the Kamiya reference. Also the primary Kamiya reference device has a narrow hole through which a guide wire is passed. Appellants' claims on appeal require a shape memory polymer foam and the Kamiya reference device could not be made of a shape memory polymer foam because the shape memory polymer foam would not provide or support a narrow hole through which a guide wire is passed.

It is respectfully requested that the rejections of Appellants' claims 1-56 on appeal be reversed and that claims 1-56 be allowed.

Respectfully submitted,

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Date: March 13, 2008

## VIII. CLAIMS APPENDIX

1. An apparatus for endovascular therapy by occluding a physical anomaly, said anomaly having an interior, comprising:
  - a shape memory material body for positioning in the interior of the physical anomaly, wherein said shape memory material body comprises a shape memory polymer foam;
  - a delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly; and
  - a system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape for occluding the physical anomaly and a secondary shape for being delivered into the interior of the physical anomaly.
2. The apparatus of claim 1 wherein said shape memory polymer foam is a shape memory polymer foam with an open cell foam structure that has pores and wherein said pores have a mean pore size between ten microns and fifty microns.
3. The apparatus of claim 1 wherein said shape memory polymer foam is a shape memory polymer foam with an open cell foam structure that has an expansion ratio in the range of 200 percent to 20000 percent.
4. The apparatus of claim 1 wherein said shape memory foam is a shape memory polymer foam composed of a polyurethane shape memory polymer with an open cell foam structure.
5. The apparatus of claim 1 wherein said shape memory polymer foam is a shape memory foam with an open cell foam structure that is composed of a polyurethane shape memory polymer having a ten percent solution of shape memory polymer in dimethyl sulfoxide.

6. The apparatus of claim 1 wherein said shape memory polymer foam is a shape memory polymer foam with an open cell foam structure including a light absorbing dye.

7. The apparatus of claim 1 wherein said delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly includes a delivery catheter, a guide wire having an end, and wherein said shape memory material body that comprises a shape memory polymer foam is at said end of said guide wire.

8. The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises radiology.

9. The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises electromagnetic energy.

10. The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises electromagnetic energy delivered optically.

11. The apparatus of claim 1 wherein said shape memory material body that comprises a shape memory polymer foam is a collapsed shape memory polymer foam device connected at the end of a guide wire.

12. The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a system for optical heating using optic fibers to transport light energy to said shape memory material body that comprises a shape memory polymer foam.



13. The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a laser and an optical fiber wherein said laser transmits laser light through said optical fiber.

14. The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a laser and an optical fiber wherein said laser transmits laser light through a multimode optical fiber.

15. The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a light absorbing material.

16. The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a light absorbing dye in an elastomeric coating on said shape memory material body that comprises a shape memory polymer foam.

17. The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises microparticles that convert RF radiation to heat.

18. The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises microparticles of a material which can selectively absorb RF radiation converting it to heat.

19. The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam

with a primary shape and a secondary shape comprises nanoparticles that convert RF radiation to heat.

20. The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises nanoparticles of a material which can selectively absorb RF radiation converting it to heat.

21. The apparatus of claim 1 wherein said shape memory material body that comprises a shape memory polymer foam comprises a shape memory polymer body that comprises a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly.

22. The apparatus of claim 1 wherein said shape memory material body that comprises a shape memory polymer foam comprises a shape memory polymer foam body having a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly.

23. An apparatus for endovascular therapy by occluding an aneurism having an interior, comprising:

shape memory polymer material body for being positioned in the interior of the aneurism, wherein said shape memory polymer material body comprises a shape memory polymer foam;

a delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism; and

an activation system for providing said shape memory polymer material body with a primary shape for occluding the aneurism and a secondary shape for being positioned in the interior of the aneurism.

24. The apparatus of claim 23 wherein said shape memory polymer material body that comprises a shape memory polymer foam is a shape memory polymer foam with an open cell foam structure that has pores and wherein said pores have a mean pore size between ten microns and fifty microns.

25. The apparatus of claim 23 wherein said shape memory polymer material body that comprises a shape memory polymer foam is a shape memory polymer foam with an open cell foam structure that has an expansion ratio in the range of 200 percent to 20000 percent.

26. The apparatus of claim 23 wherein said shape memory polymer material body that comprises a shape memory polymer foam is a shape memory polymer foam with an open cell foam structure including a light absorbing dye.

27. The apparatus of claim 23 wherein said delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism includes a delivery catheter.

28. The apparatus of claim 23 wherein said delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism includes a delivery catheter and a guide wire.

29. The apparatus of claim 23 wherein said delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism includes a delivery catheter, a guide wire having an end, and wherein said shape memory material body that comprises a shape memory polymer foam is at said end of said guide wire.

30. The apparatus of claim 23 wherein said activation system for providing said shape memory material body means with a primary shape and a secondary shape comprises radiology.

31. The apparatus of claim 23 wherein said activation system for providing said shape memory material polymer body means with a primary shape and a secondary shape comprises electromagnetic energy.

32. The apparatus of claim 23 wherein said activation system for providing said shape memory material body means with a primary shape and a secondary shape comprises electromagnetic energy delivered optically.

33. The apparatus of claim 23 wherein said shape memory polymer material body that comprises a shape memory polymer foam is a collapsed shape memory polymer foam device connected at the end of a guide wire.

34. The apparatus of claim 23 wherein said activation system for providing said shape memory polymer material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a system for optical heating using optic fibers to transport light energy to said shape memory material body that comprises a shape memory polymer foam.

35. The apparatus of claim 23 wherein said activation system for providing said shape memory polymer material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a laser and an optical fiber wherein said laser transmits laser light through said optical fiber.

36. The apparatus of claim 23 wherein said activation system for providing said shape memory polymer material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a laser and an optical fiber wherein said laser transmits laser light through a multimode optical fiber.

37. The apparatus of claim 23 wherein said activation system for providing said shape polymer memory material body that comprises a shape

memory polymer foam with a primary shape and a secondary shape comprises a light absorbing material.

38. The apparatus of claim 23 wherein said activation system for providing said shape memory polymer material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a light absorbing dye in an elastomeric coating on said shape memory material body that comprises a shape memory polymer foam.

39. The apparatus of claim 23 wherein said activation system for providing said shape memory polymer material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises microparticles that convert RF radiation to heat.

40. The apparatus of claim 23 wherein said activation system for providing said shape memory polymer material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises microparticles of a material which can selectively absorb RF radiation converting it to heat.

41. The apparatus of claim 23 wherein said activation system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises nanoparticles that convert RF radiation to heat.

42. The apparatus of claim 23 wherein said activation system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises nanoparticles of a material which can selectively absorb RF radiation converting it to heat.

43. The apparatus of claim 23 wherein said shape memory material body that comprises a shape memory polymer foam comprises a shape memory

polymer body with a secondary shape for being positioned in the interior of the aneurism and a larger primary shape for occluding the aneurism.

44. The apparatus of claim 23 wherein said shape memory material body that comprises a shape memory polymer foam comprises a shape memory polymer foam body having a secondary shape for being positioned in the interior of the aneurism and a larger primary shape for occluding the aneurism.

45. An endovascular therapy method for occluding a physical anomaly, the physical anomaly having an interior, comprising the steps of:

providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly,

positioning said shape memory polymer material body comprising a shape memory polymer foam in the interior of the physical anomaly when said shape memory polymer material body is in said secondary shape, and

causing said shape memory polymer material body comprising a shape memory polymer foam to change to said larger primary shape for occluding the anomaly.

46. The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises providing a shape memory polymer foam body with an open cell foam structure that has pores and wherein said pores have a mean pore size between ten microns and fifty microns with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly.

47. The method of claim 45 wherein said step of positioning said shape memory polymer material body comprising a shape memory polymer foam in the interior of the physical anomaly when said shape memory polymer material body comprising a shape memory polymer foam is in said secondary shape is accomplished using a catheter.

48. The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises delivering electromagnetic energy optically to said shape memory polymer material body comprising a shape memory polymer foam.

49. The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using a collapsed shape memory polymer foam device connected at the end of a guide wire.

50. The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises optical heating said shape memory polymer material body comprising a shape memory polymer foam.

51. The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises optical heating

said shape memory polymer material body comprising a shape memory polymer foam through optic fibers.

52. The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using a laser and an optical fiber to transmit laser light through said optical fiber.

53. The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using microparticles that convert RF radiation to heat.

54. The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using microparticles of a material which can selectively absorb RF radiation converting it to heat.

55. The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using nanoparticles that convert RF radiation to heat.

56. The method of claim 45 wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using



nanoparticles of a material which can selectively absorb RF radiation converting it to heat.

## IX. EVIDENCE APPENDIX

There are no entries in the Evidence Appendix.

#### **X. RELATED PROCEEDINGS APPENDIX**

There are no entries in the Related Proceedings Appendix.